*REMARKS/ARGUMENTS*

*The Pending Claims*

Claims 21, 60, and 70-89 are pending, which claims are directed to a polypeptide that comprises a particular amino acid sequence and binds with HIV gp120 under physiological conditions (claims 21, 70-77, and 86-89), and a composition comprising the polypeptide and a carrier (claims 60 and 78-85).

*Amendments to the Claims*

New claims 86-89 have been added, which are directed to a polypeptide comprising SEQ ID NOs: 12-15 with up to one conservative or neutral amino acid substitution. The new claims are supported by the claims as originally filed and by the specification, for example, at page 11, lines 16-18.

*Summary of the Office Action*

The Office rejects claims 21, 60, and 70-85 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support. All other rejections have been withdrawn. Applicant requests reconsideration of this rejection.

*Discussion of the Written Description Rejection*

The Office rejects claims 21, 60, and 70-85 as lacking written description support for a polypeptide that *comprises* one of the four recited amino acid sequences, or an amino acid sequence of SEQ ID NOs: 1-12 *with up to 6 conservative or neutral amino acid substitutions*. The Office Action states three grounds for the rejection: (a) it is allegedly "well-documented" that single amino acid substitutions, even conservative in nature, can abrogate peptide activity, (b) Applicant has not provided evidence demonstrating that a reasonable number of polypeptide variants were prepared from SEQ ID NOs: 1-12 and assessed for biological activity, and (c) the previously submitted inventor's declaration failed to address the effects that flanking sequences might have on peptide activity.

As discussed in detail below, the Office has not cited any evidence or authoritative support for its position, and has not, therefore, met its burden of establishing a *prima facie* basis for rejection under Section 112. In the absence of a *prima facie* basis for the rejection, Applicant need not proffer any evidence to rebut the Office's allegations; the rejection falls on its own. Nevertheless, Applicant submits herewith a second inventor's declaration to further support the claims. Applicant's arguments and evidence submitted herewith and already of record are sufficient to rebut the Office's stated reasons for the rejection.

*1. The Office Has Not Established a Prima Facie Case Under Section 112*

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim,* 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976); *In re Marzocchi,* 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971) (emphasis added). Furthermore, "it is incumbent upon the Patent Office ... to explain why it doubts the truth or accuracy of any statement in a supporting disclosure *and to back up assertions of its own with acceptable evidence or reasoning* which is inconsistent with the contested statement." *In re Marzocchi,* 439 F.2d at 224, 169 U.S.P.Q. at 370 (emphasis added). A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description. *Id. See also, MPEP§ 2163.04*

The Office has not provided any evidence to support its basis for rejection. The Office alleges that it is "well-documented" that even a single conservative amino acid substitution can abrogate peptide activity; however, the Office does not cite a single authority for this proposition. The Office argues that Applicant has not provided examples of variants that maintain biological activity, but provides no supported reason to doubt the statements in the Application that such variants can be created. The Office alleges that Applicant's declaration fails to address the effects that flanking sequences might have on peptide activity, yet provides no reasoning that would suggest such flanking sequences are likely to disrupt peptide function.

The Office relies solely upon unsupported allegations as a basis for its rejection, improperly attempting to shift the burden of proof to the Applicant. Thus, the Office has failed to set forth a *prima facie* case in support of the Section 112 rejection.

*2. The Claims Satisfy the Written Description Requirement of Section 112*

Although the burden of proof has not shifted to Applicant to overcome the ill-supported rejection, Applicant has nevertheless provided sufficient reasons and evidence to do so in this and earlier communications to the Office. In this regard, Applicant reasserts its prior arguments as to the Section 112 rejection, and provides the following additional comments.

Applicant previously submitted evidence, by way of the Declaration of Carl Saxinger, Ph.D. dated July 31, 2005, that one of ordinary skill in the art reading the application is armed with the knowledge of the physical and chemical properties of the amino acid residues that are available, and can readily discern which amino acids have similar chemical properties such that they would be suitable for substitution (see Declaration of Carl Saxinger, Ph.D. dated July 31, 2005, at paragraph 4; specification at page 7, line 12, through page. 8, line 11). The prior declaration also stated that an amino acid sequence containing one or more conservative substitutions retains chemical and physical properties similar to the amino acid sequence upon which it is based, and that a conservatively substituted sequence is expected to retain the function of the sequence upon which it is based at least to some degree (see Declaration of Carl Saxinger, Ph.D. dated July 31, 2005, at paragraphs 5-6).

The prior and present declarations explain that the Examples provided in the application demonstrate not only that the claimed sequences bind gp120, but that particular portions of the claimed sequences bind gp120 to a greater or lesser degree, or not at all (see Declaration of Carl Saxinger, Ph.D. dated July 31, 2005, at paragraphs 7-8; Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraph 3). This information, as read by one of ordinary skill in the art, provides specific guidance as to which amino acid residues of the claimed sequences are candidates for substitution without abrogating binding activity (see Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraph 4).

The application, thus, adequately describes a variant of SEQ ID NOs: 12-15 with up to six conservative or neutral amino acid substitutions, and certainly provides an adequate description of such variants comprising up to one conservative or neutral amino acid substitution as recited in the new claims.

Regarding the effect of flanking sequences on the binding activity of SEQ ID NOs: 12-15, the incorporation of biologically active sequences into larger molecules was state of the art at the time the application was filed (see Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraphs 9-10). It would be the rare instance that a flanking sequence would be chosen that would have the necessary primary, secondary, and tertiary structure needed to abrogate peptide function (see Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraph 11). This is especially true given the general knowledge and tools available at the relevant time (see Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraph 11). Furthermore, it was within the skill of the ordinary researcher during at the relevant time to chose effective flanking sequences and test such constructs using no more than routine experimentation (see Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraph 12).

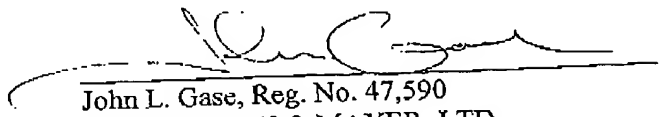
Moreover, contrary to the Office's assertions, the Examples provide evidence of the effect that flanking sequences would have on SEQ ID NOs: 12-15 in at least two respects. First, the sequences described in the Examples were tested by linking the sequences to a larger polylysine backbone molecule (see Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraph 5). Thus, the tested sequences, in fact, contained one or more "flanking" amino acid residues (see Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraph 5). Furthermore, the sequences were tested as a transitioning sequence offset format. In other words, each sequence tested contained part of the preceding sequence to which four additional amino acids are added to the carboxyl-end of the sequence, and four amino acids are effectively removed from the amino-end of the sequence (see Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraphs 6-7). In this respect, the Examples demonstrate the effect of flanking sequences (see Declaration of Carl Saxinger, Ph.D. dated May 23, 2006, at paragraphs 6-7).

For the foregoing reasons, the subject matter of the pending claims meets the written description requirement of Section 112, first paragraph. Accordingly, the rejection should be withdrawn.

*Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



John L. Gase, Reg. No. 47,590
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: May 23, 2006